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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

| EXAMINER | |
|---|---|
| HENDRICKS, KEITH D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1761 | |

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/750,990 | SOE, JORN BORCH | |
| | Examiner | Art Unit | |
| | Keith Hendricks | 1761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *44-59 and 61-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-59 and 61-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-59, and 61-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "said second functional ingredient", as added in the amendment of September 04, 2003, lacks a clear antecedent basis within the claims. Applicant has amended the independent claims to state that "an emulsifier and a second ingredient" are produced; however, the subsequent use of the phrase "said second *functional* ingredient" does not correspond to the initial phrase. Applicant is encouraged to amend the claims to maintain continuity throughout, especially given the use of such phrases as "second constituent" and "second ingredient", etc. Note the discussions previously on the record, regarding "second functional ingredient".

Claims 61-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language. These claims are omnibus type claims, and are indefinite, as they depend from a canceled claim (60). Due to the varying subject matter within these claims, it is unclear from which claim(s) they should now depend, or if they were intended to be canceled along with claim 60 from which they depend, and *thus they have not been further examined on the record against the prior art.* Note that amendment of these claims subsequent to this action would raise new issues of search and/or consideration after final.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**(1)** Claims 44-53 and 60 and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Den Ouweland et al. (US PAT 5,695,802, of record). The reference and rejection are taken as cited in a previous Office action.

*Note that claims 61-68 have not been further examined on the record against the prior art. See the rejection under 35 U.S.C. 112, second paragraph, above.*

Applicant's arguments filed September 04, 2003, have been fully considered but they are not persuasive. At page 10 of the response, applicant states that "claim 44 has been amended to recite that the emulsifier and the second functional ingredient are generated by alcoholysis." Applicant refers to a dictionary definition of the term "alcoholysis", and further states that "the term 'alcohol' does not encompass water, as water does not comprise an 'alkyl' group. Thus, the term 'alcoholysis' does not encompass hydrolysis".

This is not deemed persuasive for the reasons of record. During prosecution, reliance upon a dictionary definition of a term is made when the definition provided in the specification is unclear, or does not exist. However, neither is the case with regard to the instant application, as applicant has clearly provided the definition upon which they choose to rely. Initially, lines 5-9 of page 15 of applicant's specification state (underlining added):

> Preferably, the functional ingredient of the present invention is generated by a reaction selected from alcoholysis, preferably glycerolysis, hydrolysis, interesterification, and combinations thereof More preferably the functional ingredient is generated by a alcoholysis reaction, preferably a glycerolysis reaction.

This passage lists the preferred types of reactions generated by the "enzyme having esterase activity". Alcoholysis is stated to be the generic reaction, where glycerolysis and hydrolysis are among the types of enzymatic reactions recited under the generic alcoholysis reaction.

At page 11, lines 29- 31, the specification states that:

> Preferably, the second constituent of the food material/foodstuff is selected from a constituent comprising a hydroxy group (-OH), polyvalent alcohols, including glycerol; water, ethanol sugars including sucrose, fructose, glucose (dextrose), lactose...

Thus, applicant's statement in the current amendment that the claimed reactions do not include water, and that "the term 'alcoholysis' does not encompass hydrolysis", is incorrect, in that it clearly conflicts with their own specification.

Secondly, applicants' arguments appear to conflict with known enzymatic reactions. The *only* set of enzymes which can catalyze the claimed reaction, are the hydrolases (of which there are hundreds, if not thousands), and included therein, are the esterases such as carboxylic ester hydrolases, which include lipases. The general reaction of any carboxylic ester hydrolase is as follows:

Carboxylic ester + a component with a hydroxy group (-OH) = an alcohol + a carboxylate-containing component.

The general reaction of a lipase, which is a subset of the carboxylic ester hydrolases, and thus of esterases, and thus of hydrolases in general, is as follows:

Triacylglycerol + a component with a hydroxy group (-OH) = diacylglycerol + a carboxylate-containing component.

The broadly-recited terms of the instant claim language may be summarized to correspond to this reaction as follows:

"Fatty acid ester": Triacylglycerol, i.e. a triglyceride.

"Second constituent comprising a hydroxy group": water or another component with a hydroxy group (-OH).

"emulsifier" : diacylglycerol, i.e. a diglyceride.

"second (functional) ingredient": a carboxylate-containing component.

Thus, applicant's claimed reaction within a foodstuff ***is the same reaction*** of any known esterase. The natural activity of any lipase (an esterase) begins with two substrates, one a fatty acid ester, and the other a hydroxy group substrate (including $H_2O$), and inherently and necessarily produces two different products, one of which is a different fatty acid ester, which may act as emulsifiers in food compositions.

Applicant's comments that "Van Den Ouweland is directed to the preparation of an ingredient to be added to food, i.e., a 'flavoring composition' which is prepared by hydrolysis", and that the reference "does not teach or suggest a process for preparing a foodstuff that results in the *in situ* formation of two functional ingredients and which are generated by alcoholysis", are not deemed persuasive for the reasons of record. Applicant is referred to their own examples, which state that the resultant "reaction mixture is used for ice cream", or for margarine, sponge cake, filling cream, etc. Not one of applicant's working examples actually adds the enzyme directly to a final food product composition, nor even to a mixture containing all of the ingredients of the final food product. Every one of applicant's examples does,

however, involve the addition of the enzyme to a fatty-acid component, and then subsequently adding the resultant (hydrolyzed) component to a final food composition. As applicant has accurately stated, this is also the method performed by the reference. Nevertheless, it is true that the teachings of applicant's specification need not be limited to the examples. Therefore, reference to lines 8-10 at page 14 of the specification provides the statement that "the conversion agent [i.e. esterase] may be contacted with the [sic] of the food material or a portion thereof." Applicant's claims *do not* specifically state that the enzyme is added to the final, total composition of the foodstuff, as applicant argues. At best, applicant's claims recite (i) "contacting a food material... with an enzyme", where the food material only need possess the fatty acid ester and second constituent, and (ii) "inactivating or denaturing the enzyme to provide the foodstuff...". Page 14, lines 19-22 of the specification state that:

> An Example of a portion of the food material being contacted with the conversion agent and the contacted material subsequently being contacted with the further constituents of the food material is exemplified in Figure 1 (Flow diagram for *in situ* production of emulsifier).

Whether the "*in situ* production" of an emulsifier is specifically claimed or not, this passage of the specification demonstrates that the process may indeed encompass the enzymatic reaction "of a portion of the food material" alone, and as such, the claims are not limited as applicants suggest.

Furthermore, at page 16 of applicants' own specification, it is stated that "the foodstuff may comprise an emulsion of oil and water." No other components are required, and thus applicants' arguments are not deemed persuasive for the reasons of record.

NOTE: As previously suggested on the record, in order to reduce the issues of the prosecution of this application, applicant is encouraged to carefully review the specification and claims, such that the arguments submitted are commensurate in scope with the support provided therein. Careful consideration to amending the claims to more specifically and accurately reflect applicant's invention, is suggested.

**(2)** Claims 44-61 and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Olesen et al. (WO 94/040035, of record). The reference and rejection are taken as cited in a previous Office action.

*Note that claims 61-68 have not been further examined on the record against the prior art. See the rejection under 35 U.S.C. 112, second paragraph, above.*

Applicant's arguments filed September 04, 2003, have been fully considered but they are not persuasive. At page 10 of the response, applicant states that because the "claims do not refer to baked products and/or dough", the reference no longer anticipates the claims.

This is not deemed persuasive. Applicant's claims state that "the foodstuff is selected from the group consisting of confectionery, frozen products, dairy products, meat products, edible oils and fats and fine foods." At pages 6 and 10 of the reference, it is clearly stated that the "lipase forms an 'in situ' emulsifier comprising mono- and diglycerides in dough." The dough or dough improver ingredients may comprise added fat (pg. 14). Thus, this anticipates the claimed invention, in that the fats therein read upon "edible oils and fats", as claimed. As stated above with regard to the Van Den Ouweland et al. reference, whether the "*in situ* production" of an emulsifier is specifically recited in the claims or not, page 14, lines 19-22 of the specification demonstrate that the process may indeed encompass the enzymatic reaction "of a portion of the food material", and as such, the claims are not limited as applicants suggest. Furthermore, the term "confectionery" is not defined by the specification, and so reference to Webster's Ninth New Collegiate Dictionary defines "confectionery" as "sweet foods (as candy or pastry)". Page 12, lines 11-19 of Olesen et al. states that the term "baked product" encompasses such things as breads and cakes. As cakes are considered pastries in the art, the reference anticipates the claims. Finally, the term "fine foods" is not defined by the specification, and it is unclear as to what is encompassed by this phrase; however, absent any clear and convincing evidence and/or arguments to the contrary, one of ordinary skill in the art would consider certain items recited at page 12 of the reference, namely "French baguette-type bread" and "cakes", as "fine foods". Thus, contrary to applicant's arguments, baked products are encompassed by the instant claims, and thus anticipated by the reference. Furthermore, the specification does not provide support for a negative limitation specifically excluding these items.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3602 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KEITH HENDRICKS
PRIMARY EXAMINER